

TRANSMITTAL DOCUMENT

1. Name and Address of Submitter (Registrant):

EPA Company No. 11556

Elanco US Inc
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2. Regulatory Action for which this package is submitted:

Response to 6(a)(2) request for additional information related to PNR 1427 Insecticide (ABN Seresto; EPA Reg. No. 11556-155)

3. Transmittal Date:

May 18, 2021

4. List of Submitted Documents:

MRID NUMBER	VOLUME NUMBER	EPA STUDY TITLE	GUIDELINE NUMBER
<u>51580500</u>	ADMIN	<u>Administrative Materials</u> Submission cover letter Transmittal document Certification with respect to citation of data Document index Data matrix – confidential and sanitized versions	-----
<u>NA</u>	1 of 14	Seizure occurrence in dogs under primary veterinary care in the UK: prevalence and risk factors. Erlen, et al; 2018.	NA
<u>NA</u>	2 of 14	Literature review and expert statement on the epidemiology or the frequency and convulsions in dogs in general and in different breeds. Potschka; 2016.	NA
<u>NA</u>	3 of 14	Clinical Characteristics and Inheritance of Idiopathic Epilepsy in Vizslas. Patterson, et al; 2003.	NA
<u>NA</u>	4 of 14	Neuropathology of Canine Epilepsy. Koestner; 1989.	
<u>51580501</u>	5 of 14	Target Animal Safety with a 10% Imidacloprid + 4.5% Flumethrin Collar with or without Reflector Clips When Applied Once to Adult Cats	NA

<u>51580502</u>	6 of 14	Longterm Target Animal Safety of a Single Application of a 10% Imidacloprid + 4.5% Flumethrin Collar with Reflectors on Cats	NA
<u>51580503</u>	7 of 14	Longterm Target Animal Safety of a Single Application of a 10% Imidacloprid + 4.5% Flumethrin Collar with Reflectors on Adult Dogs	NA
<u>51580504</u>	8 of 14	Pharmacokinetics of Flumethrin in the Hair of Dogs after Application of a Collar Containing 10% Imidacloprid Plus 4.5% Flumethrin in Comparison to a Collar Containing 10% Propoxur Plus 2.25% Flumethrin (Kiltix Collar)	NA
<u>51580505</u>	9 of 14	Risk assessment on skin and eye irritation and skin sensitization of the formulants	NA
<u>51580506</u>	10 of 14	User Risk Assessment, March 2011, Imidacloprid/Flumethrin Collar	NA
<u>51580507</u>	11 of 14	ORE and Risk Assessment for Seresto Dog and Cat Collars Formulated with Imidacloprid and Flumethrin	NA
<u>51580508</u>	12 of 14	PMRA: Correlation of case reports to the exposure of AI from Seresto collar	NA
<u>51580509</u>	13 of 14	Child resistance of reflectors	NA
<u>51580510</u>	14 of 14	Statement on safety observations in clinical studies for Seresto in cats and dogs	NA

5. Company Contact:

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Company Representative:

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